

<b>Case Number:</b>	CM13-0071427		
<b>Date Assigned:</b>	01/08/2014	<b>Date of Injury:</b>	05/27/2009
<b>Decision Date:</b>	08/18/2014	<b>UR Denial Date:</b>	11/26/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/27/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Preventative Medicine, has a subspecialty in Occupational Medicine, and is licensed to practice in Iowa. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This patient is a 72 year old employee with date of injury of 5/27/09. Medical records indicate the patient is undergoing treatment for osteoarthritis of the knee. Subjective complaints include back, knee, and leg pain. The patient has constant throbbing, gnawing, and aching in both knees. The patient pointed out the anterior and posterior aspect of both knees as having pain. She reports constant low aching back pain that radiates and tingles into the feet with no localization. Functionally, she says she can't sit, stand, walk, lay down, or drive. The pain is made worse by sitting, standing, or walking. Pain is rated as 8/10. Objective findings include an unsteady and antalgic gait. She could not get on her heels and toes. Treatment has consisted of Tapentadol, Atenolol, Norco, Zoloft, Valium, Januvia Oral, Zantac, Nucynta, Lisinopril, Bentyl, and right knee local anesthetic/steroid.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**120 TAPENTADOL (NUCYNTA) 50MG:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 74-96. Decision based on Non-MTUS Citation Official Disability Guidelines.

**Decision rationale:** Nucynta is classified as a second line opioid. The MTUS does not discourage use of opioids past two weeks, but states that ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects should take place. Pain assessment should include current pain, the least reported pain over the period since last assessment, average pain, intensity of pain after taking the opioid, how long it takes for pain relief, and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. The Official Disability Guidelines state that Nucynta is recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. Recent large randomized controlled trials concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. On November 21, 2008, the FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. Nucynta, manufactured by [REDACTED], is a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. Nucynta was made a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. Nucynta may be abused by crushing, chewing, snorting, or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. Gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine; however, the manufacturer disagrees. In August 2011, the FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. While the treating physician has documented pain relief and improved functioning from Norco, the treating physician has not documented intolerable side effects, such as complaints of constipation, nausea, and/or vomiting. The treating physician has not provided medical documentation of intolerable side effects to justify the switch to Nucynta (a second line opioid medication) rather than another first line opioid medication. As such, the request is not medically necessary.